

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation Number: 5823

Douglas BEIGEL

Application No.: 10/665,511

Group Art Unit: 3714

Filed: September 22, 2003

Examiner: Robert J. UTAMA

For: **ONLINE SYSTEM AND METHOD FOR ASSESSING/CERTIFYING
COMPETENCIES AND COMPLIANCE**

DECLARATION UNDER 37 CFR §1.132

Mail Stop Amendment
P.O. Box 1450
Commissioner for Patents
Alexandria, VA 22313-1450

Dear Commissioner:

I, **Douglas Beigel**, a citizen of the UNITED STATES OF AMERICA, hereby declare:

1. I am the Inventor of the subject matter claimed in U.S. Patent Application No. 10/665,511 ("the '511 Application"), which was filed in the U.S. Patent and Trademark Office on September 22, 2003. The '511 Application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application No. 60/411,865, which was filed in the U.S. Patent and Trademark Office on September 20, 2002, of which I am also the Inventor.
2. I am also the Chief Executive Officer of COLA, the Assignee of the '511 Application.
3. This Declaration is submitted responsive to the Examiner's Request of Information under 37 CFR 1.105 in the Office Action mailed October 5, 2009 by the U.S. Patent and Trademark Office.
4. The Examiner has asserted that "[t]he information is required to identify products and services embodying the disclosed subject matter of an online system to insure compliance and certification found in the prior art. The examiner notes that the assignee's website seems to indicate that the program and the online education program to insure compliance and certification has been available since July 21, 2001 (see NPL evidence). As such, the

examiner would need to see all of the documents related to the COLA's laboratory accreditation program." See Office Action page 14, item 18 (repeated on pages 15-16, item 26). Accordingly, Applicant and the Assignee of the '511 Application provide the attached documents to be fully responsive to the Examiner's Request.

5. The exhibit included in Appendix A is a copy of the *COLA Accreditation Manual*. The paper manual (first offered on a CD-ROM in 2007) is given to all registered participants of COLA's laboratory accreditation program, a predecessor of the commercial embodiment of the subject matter recited in independent claims 1, 11, and 22 of the '511 Application. This is the most relevant document related to COLA's laboratory accreditation program.
6. Appendix A also includes a portion of the only other document directly related to COLA's laboratory accreditation program. In Section Five of the *COLA Accreditation Manual*, a copy of *LabGuides* is included. The *LabGuides* were developed for those enrolled in the COLA laboratory accreditation program and were included as part of the *Accreditation Manual* which all enrollees received. The *LabGuides* reference both the Clinical Laboratory Improvement Amendments (*CLIA*) [federal] regulation requirements and COLA accreditation requirements and provide information on laboratory topics including "Contents of a Procedure Manual", "Finding a Laboratory Consultant" and "Lab Safety." The *LabGuides* were merely paper products that explained good laboratory practices to the lab and, in some instances, COLA requirements (i.e. underlined text as explained in the margin of the *LabGuide*). These were also not tied to any specific questions as found in Section Four of the *Accreditation Manual*.

As an explanatory note on the *LabGuides*, the *Accreditation Manual* Section Five table of contents lists *LabGuides* 1 to 19, 20 to 39, 50 to 69 and 70 to 79. The numbering system was developed using a series of numbers for different topics, i.e. numbers 1-19 were reserved for issues relating to lab administration - but only 11 guides were developed; had another guide been developed it would have been number 12. The purpose of the numbering system was to keep the same topics together which would not have been possible had they all been numbered consecutively. For example, *LabGuides* 20-39 were for testing/specialties - but the related *LabGuides* were only developed up to #32, Quality Control was designated to *LabGuides* 50-69 - but the related *LabGuides* were only developed up to #55, etc. Only *LabGuides* 1-11, 20-32, 50-55 and 70 are included in the *Manual*; the omitted *LabGuides* 12-19, 33-49, 56-69 and 71-79 were not developed and did not exist at the time of publication of the *Manual* in 2000.

7. The exhibit included in Appendix B is a copy of the application form for COLA's laboratory accreditation program, in use in 2000 that was available on <http://www.cola.org>. Please note that the application was merely an electronic copy of a paper form with no online links or interactive features, other than a submit feature.

8. The exhibit included in Appendix C is a listing of COLA “Educational Products” available in 2000. This listing is accessible via the COLA.org homepage, and includes the *COLA Guide to Quality Assurance* exhibit of Appendix E, the *Laboratory Accreditation Manual* exhibit of Appendix A, *COLA LabFacts*, and *CLIAFacts for Laboratories* exhibit of Appendix D.
9. *COLA LabFacts* were developed by COLA as a product for sale to laboratories that were not enrolled in the accreditation program. Therefore, the *LabFacts* were sold separately from the accreditation related materials discussed above, and did not contain references to the COLA accreditation program. The topics were similar to the *LabGuides*, in that they explained good laboratory practices. As suggested on pages 3-4 of the exhibit of Appendix C, the *LabFacts* were sold either as a bound volume of the full series of 27 *LabFacts*, or individually.
10. The exhibit included in Appendix D is a copy of the *COLA CLIAFacts for Laboratories* educational product, of March 2001. *CLIAFacts* were one or two page sheets about specific federal (CLIA) requirements which were also intended as an educational resource for labs not enrolled in COLA’s accreditation program. These papers on good lab practices were not tied to any specific criteria or accreditation questions from any accreditation program. The title refers to the federal law, CLIA, and not COLA.
11. The exhibit included in Appendix E is a copy of the *COLA Guide to Quality Assurance in the Clinical Laboratory*, in use since 1994.
12. Other educational documents are available; however, they are general in nature, based upon either “best practices” or specific federal regulations. These documents tie directly to COLA’s educational outlook on laboratory medicine as evidenced by its mission statement:

COLA is a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.

Applicant and Assignee have made every effort to obtain copies of “all of the documents related to the COLA’s laboratory accreditation program” around the time period of the priority date and filing date of the ‘511 Application. If the Examiner requires any further specific documents, Applicant and Assignee can attempt to procure them and supply them to the Examiner.

13. As part of the Request for Information, the Examiner has specifically requested:

14. "In response to this requirement, please provide the names of any products or services that have incorporated the claimed subject matter." *See* Office Action page 14, item 19 (repeated on page 16, item 27).

Applicant and Assignee believe that COLA's laboratory accreditation program is the only service incorporating the claimed subject matter.

15. "In response to this requirement, please provide the title, citation and copy of each publication that any of the applicants relied upon to develop the disclosed subject matter that describes the applicant's invention, particularly as to developing the laboratory accreditation program." *See* Office Action page 14, item 20 (repeated on page 16, item 28).

Applicant and Assignee are not aware of any publications relied upon to develop the disclosed subject matter.

16. "For each publication, please provide a concise explanation of the reliance placed on that publication in the development of the disclosed subject matter." *See* Office Action page 14, item 21 (repeated on page 16, item 29).

In view of Applicant and Assignee's response to the previous question, this question is not applicable.

17. "In response to this requirement, please state whether any search of prior art was performed. If a search was performed, please state the citation for each prior art collection searched. If any art retrieved from the search was considered material to demonstrating the knowledge of a person having ordinary skill in the art to the disclosed 09/20/2001, please provide the citation for each piece of art considered and a copy of the art." *See* Office Action pages 14-15, item 22 (repeated on page 16, item 30).

A search of prior art was performed at the U.S. Patent and Trademark Office against U.S. patent and U.S. patent application publication art collections. The art retrieved from the search included:

U.S. Patent No. 5,697,789;
U.S. Patent No. 5,823,781;
U.S. Patent No. 6,816,702;
U.S. Patent No. 6,947,914;
U.S. Patent No. 7,085,679;
U.S. Patent No. 7,162,198;
U.S. Patent Application Publication No. 2002/0099586;
U.S. Patent Application Publication No. 2002/0133502;
U.S. Patent Application Publication No. 2004/0230989;

U.S. Patent Application Publication No. 2005/0028005;
U.S. Patent Application Publication No. 2005/0228685; and
U.S. Patent Application Publication No. 2006/0199165.

Each of these references is or has been cited to the Examiner in the form of an Information Disclosure Statement. Copies of U.S. Patents/Publications are not supplied as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

18. Applicant and the Assignee are not aware of additional information that may be pertinent to the Examiner's Request. For example, regarding an IT "Dictionary List," neither Applicant nor the Assignee have such a document that shows the progression of the various features or parts of the commercial embodiment of the claimed subject matter as it was implemented.
19. As discussed above, the exhibits included in Appendix A-E are or refer to physical paper documents that could be requested by users of the COLA laboratory accreditation program, a predecessor of the commercial embodiment of the subject matter recited in independent claims 1, 11, and 22 of the '511 Application. Independent claim 1 (as last presented to the Examiner) recites:

A system for allowing a user to perform an assessment for compliance certification comprising:

a database storing a plurality of evaluation questions and a plurality of assessment questions,
wherein the evaluation questions ask for information used to construct profiles of at least one organization, each profile comprising substantive work-function related information of the at least one organization, at least one of the substantive work-function related information selected from the group consisting of: tests performed, specialties, instruments, personnel, and proficiency testing of the at least one organization,
wherein the assessment questions ask for information used to determine if said at least one organization meets requirements for at least one compliance certification, and
wherein subsets of said plurality of evaluation and assessment questions are combined to form a plurality of assessment courses; and
a server, connected to said database via a communications network, having a processor configured to cause a graphical user interface to be displayed to a network access device connected to said server via said communications network;
wherein said processor is further configured to present to an assessed user, as individual personnel of an organization seeking said at least one compliance certification, via said graphical user interface, a subset of evaluation questions comprised by at least one of said plurality of assessment courses,
wherein said processor is further configured to receive responses from the

assessed user to said subset of evaluation questions,
wherein said *processor* is further configured to *construct* at least one profile...
(emphases added).

Independent claims 11 and 22 are directed to a method and a computer program product, respectively, reciting features discussed in claim 1.

20. The Office Action mailed October 5, 2009 rejects pending claims under the Examiner located “NPL evidence” of webpages from *cola.org* (accessed via the “Internet Archive Wayback Machine”) in combination with other references. In telephone Interview(s) conducted between Applicant’s Representative and the Examiner, COLA has been asked to provide a “manual” to show that the claimed subject matter was not in use prior to one year before the earliest effective filing date of the ‘511 Application, i.e. prior to September 20, 2001.
21. Applicant and Assignee note that the ‘511 Application claims the benefit under 35 U.S.C. § 119(c) of U.S. Provisional Patent Application No. 60/411,865, which was filed in the U.S. Patent and Trademark Office on September 20, 2002. Accordingly, the effective “one-year bar” date for Applicant’s claimed subject matter is September 20, 2001.
22. Applicant and Assignee respectfully submit that Examiner’s reliance on an online web search from the “Internet Archive *WaybackMachine*” as evidence of “prior art” is in error.
23. With respect to the assertions regarding *cola.org*: An examination of numerous archived web pages accessed in a similar manner as those cited by the Examiner (“NPL evidence”) from archived pages of *cola.org* (including fully accessible pages from the first year available, December 2, 1998, thru August 17, 2000, one year prior to September 20, 2001 [excepting June 20, 2000 where the link is to a non-related homepage]; and web pages linked to partially non-accessible information from December 7, 2000, April 5, 2001, May 16, 2001 and July 21, 2001) shows that COLA allowed its customers to:
 - a. File an application (*see* exhibit of Appendix B) to enroll in COLA’s Laboratory accreditation program which is the *predecessor* of, and not the subject matter of, the patent. The online form was simply a substitute for a paper application.
 - b. Gain reference to educational products (*see* exhibits of Appendices C-E, discussed in items 8-11 above). This was also simply a way that anyone could order paper copies of a limited number of educational products that were of interest to anyone who worked for or operated a clinical laboratory. There was no physical, automated or causal connection between the few paper educational products and the almost 300 possible criteria which formed the basis of the inspection to accredit laboratories. *See* Section Four of the *COLA Accreditation Manual*.

24. The exhibit included in Appendix F is a copy of the press release dated January 9, 2002. Applicant and Assignee note that similar statements were on the COLA.org and LabUniversity.org websites in January 2002.
25. With respect to the assertions regarding labuniversity.org: Applicant and Assignee respectfully submit that the Examiner's assertions that web pages of COLA's online service, *LabUniversity.org*, predate one year before the earliest effective filing date of the '511 Application are also in error.
- a. COLA did not release Lab University until January 2002, which is notably *after* the effective "one-year bar date" of the '511 Application.
 - b. When Lab University was launched, its stated purpose was:
COLA has initiated a Distance Learning Program in response to the learning needs of physicians and laboratory clinicians for easily accessible, benchmark training in quality laboratory practices.
See also exhibit of Appendix F.
Therefore, the Lab University courses were general in nature for any clinician *whether they were enrolled in COLA's accreditation program or not.*
 - c. COLA is not seeking a patent on the concept of distance learning. As with the *printed paper* educational products discussed above, the courses that were developed were *general in nature* for general laboratory practices and could be utilized by anyone working in a clinical laboratory environment.
 - d. The LabUniversity Courses offered at the initiation were:
 - 1. Laboratory Director Program
 - 2. Quality Control in the Clinical Laboratory
 - 3. OSHA Safety Requirements for the Physician Office Laboratory
 - 4. CLIA '88 Requirements for the Clinical Laboratory
 - 5. Later courses added were
 - a. Practical Proficiency Testing
 - b. Basics of Quality Assurance
 - c. Quality Control for Microbiology

These courses were all general to the laboratory industry and *could be taken by anyone whether they were enrolled in COLA's accreditation program or not.*
 - e. The drawings (illustrative screen-shots) included in the '511 Application (e.g. figures 5A, 5I and 5J) were merely meant to be examples to provide a visual image of the final product. The screen-shots were taken from the online learning system COLA developed in conjunction with a platform developed by Avilar, whose copyright notice can be clearly seen at the bottom of the figures. In hindsight, COLA should have removed the non-descriptive name "LabUniversity" and substituted a generic name such as "Link to Online Products."

26. The exhibits included in Appendix G are screen shots of webpages accessed using the “Internet Archive Wayback Machine” for cola.org, with respect to ‘Application’ information, for various dates before, around and after the pertinent “one-year bar,” effective filing and priority date(s) of the ‘511 Application.
27. With respect to the clear differences between the Application Form asserted by the Examiner from page 7 of the “NPL evidence” and the Form of the exhibit of Appendix B:

Firstly, the Examiner-accessed form is copyrighted “© COLA: 3/02 R,” which suggests that the form is from March 2002, which is *after* the “one-year bar date” based on the earliest effective filing date of the ‘511 Application.

Secondly, the type of the Examiner-accessed form is referred to internally within COLA as a “teleform ®” because it can be fed through a flatbed scanner and populate a database rather than have someone key it in. Thus, it is clear that the Examiner-accessed form does not provide *user* interactivity as in the context of the claimed subject matter of the ‘511 application.

Furthermore, the “NPL evidence” provided by the Examiner suggests that the Examiner-accessed the 3/02 Application (as shown in Appendix G) via:

- a. Search results for <http://cola.org> on the “Internet Archive Wayback Machine”
http://web.archive.org/web/*/http://cola.org
 - b. the “Internet Archive Wayback Machine” archived homepage for “cola.org” for Jul 21, 2001
<http://web.archive.org/web/20010711081612/www.cola.org/default.asp>
 - c. accessing “Laboratory Accreditation”
<http://web.archive.org/web/20010619213859/www.cola.org/prodsandservs/labaccred.asp>
 - d. accessing “click here”
<http://web.archive.org/web/20010708102632/www.cola.org/forms.asp>
 - e. accessing “Independent Laboratory”
<http://web.archive.org/web/20010708102632/http://www.cola.org/storage/iap00a.pdf>
- However, the last file is not accessible on the Wayback machine. Any attempts to alter the web address to match the “wiap00a.pdf” form lead to the **March 2002** form.

However, the 3/02 Application *is* accessible (as *seen* in Appendix G) via:

- a. Search results for <http://cola.org> on the “Internet Archive Wayback Machine”
http://web.archive.org/web/*/http://cola.org
- b. the “Internet Archive Wayback Machine” archived homepage for “cola.org” for Sep 25, 2001 (which **does not** pre-date the “one-year [effective] bar date” of the ‘511 Application)
<http://web.archive.org/web/20010925000115/http://cola.org/>

- c. accessing “Laboratory Accreditation”
<http://web.archive.org/web/20011110182633/cola.org/prodsandsrvs/labaccred.asp>
- d. accessing “click here”
<http://web.archive.org/web/20020619054256/cola.org/forms.asp>
- e. accessing “Independent Laboratory”
<http://web.archive.org/web/20030322091645/www.cola.org/storage/wiap00a.pdf>

In contrast, the form submitted as an exhibit in Appendix B *is* accessible for any date *prior to* Sep 25, 2001 and even dates *prior to* the “one-year [effective] bar date” of the ‘511 Application, i.e. for example at least from the first date (i.e. Dec. 02, 1998) for which the “Internet Archive Wayback Machine” returns a search result for <http://cola.org> to Aug 17, 2000. As *seen* in Appendix G:

- a. Search results for <http://cola.org> on the “Internet Archive Wayback Machine”
http://web.archive.org/web/*http://cola.org
 - b. the “Internet Archive Wayback Machine” archived homepage for “cola.org” for Dec 02, 1998
<http://web.archive.org/web/19981202165047/http://www.cola.org/index.html>
 - c. accessing “Application Info”
<http://web.archive.org/web/19981206151726/www.cola.org/applicinfo/moreinfo.htm>
- and
- a. Search results for <http://cola.org> on the “Internet Archive Wayback Machine”
http://web.archive.org/web/*http://cola.org
 - b. the “Internet Archive Wayback Machine” archived homepage for “cola.org” for Aug 17, 2000
<http://web.archive.org/web/20000817025957/http://www.cola.org>
 - c. accessing “Application Info”
<http://web.archive.org/web/2000829095956/www.cola.org/applicinfo/moreinfo.htm>

Each of these search paths lead to the form provided in the exhibit of Appendix B.

- 28. Thus, *there is no evidence that the Examiner-asserted form was used by COLA prior to* September 20, 2001, or that the Examiner asserted form existed prior to March 2002. Notably, the terms from the Examiner asserted form that are being relied upon, in combination with other references, to reject the claimed subject matter *are not present on the exhibited form of Appendix B* (i.e. prior to the “one-year [effective] bar date” of the ‘511 Application).
- 29. The Examiner is relying on the listing of “the following specialties” [lower left corner of Examiner asserted form] “Chemistry... Hematology... Microbiology... Immunology...” to supplement the asserted grounds of rejection taken from the Singer and Haunschild references. The Examiner has admitted that the Singer reference is deficient with respect to disclosing that

“each profile compris[es these claimed specialties].” However, *even if* these specialties ‘found’ by the Examiner *could be applied* to reject the claimed subject matter of the ‘511 Application (i.e. if the form predated the “one-year [effective] bar date” of the ‘511 Application), these ‘specialities’ should only be taken in context as *listed* on an *online form* that can be submitted to apply for a traditional *paper/physical* accreditation. This is in contrast to the claimed features *as a whole* [**regarding computer-based user-responsive compliance certification**] as discussed in item 18 above.

30. Thus, Applicant and Assignee believe that the Examiner’s Request for Information has been fully complied with, and that the documents and issues discussed above support the novelty and patentability of Applicant’s claimed subject matter, at least because it shows that the Examiner asserted “NPL evidence” is not applicable as prior art, for the reasons discussed above.
31. All statements made herein of my own knowledge are true, and are based upon information are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both under the provisions of 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Douglas Beigel

Date

Chief Executive Officer
COLA

Appendix A (COLA Accreditation Manual – Revision No. 6: June 2000)

Appendix B (“For COLA Application Information...” ‘Application Form’)

Accessed via the “Internet Archive Wayback Machine”

Appendix C (Listing of COLA “Educational Products”)

Accessed via the “Internet Archive Wayback Machine”

Appendix D (*COLA Guide to Quality Assurance in the Clinical Laboratory*)

Appendix E (*COLA CLIA Facts for Laboratories*)

Appendix F (Press Release Announcing COLA Online Courses)

Accessed via the "Internet Archive Wayback Machine"

**COLA Introduces
On-Line Courses for
Continuing
Education in
Healthcare**

Date: 01/09/2002

News Item: FOR IMMEDIATE RELEASE
CONTACT: Julie A. Owings, (410) 381-6581
02-15

COLA, a national healthcare accreditation organization, introduces its latest product: LabUniversity. LabUniversity, located at www.LabUniversity.org, is a distance learning program that was created by COLA in response to the learning needs of physicians and laboratory staff to obtain convenient laboratory training that will meet certification and licensing requirements. LabUniversity is an educational resource that can be used anytime, anywhere, via the Internet.

Lessons are designed to take between 20 and 30 minutes to complete, and courses are drawn from current laboratory practice. Courses include topics such as:

- Quality Control
- Quality Assurance
- Proficiency Testing
- CLIA '88 Requirements
- Laboratory Personnel Requirements
- OSHA Requirements
- And more courses to meet your continuing education needs.

Appendix G (“Internet Archive Wayback Machine” archived pages from cola.org)

Accessed from the “Internet Archive Wayback Machine” archived homepage for “cola.org” for
Jul 21, 2001

Accessed from the “Internet Archive Wayback Machine” archived homepage for “cola.org” for
Sep 25, 2001

Accessed from the “Internet Archive Wayback Machine” archived homepage for “cola.org” for
Dec 02, 1998

Accessed from the “Internet Archive Wayback Machine” archived homepage for “cola.org” for
Aug 17, 2000